AMENDED CLAIMS
[received by the International Bureau on 12 September 2005 (12.09.2005);
original claims 1-28 amended (4 pages)]

What is claimed is:

1. An isolated compound, which is topotecan monohydrochloride pentahydrate, said compound having an x-ray diffraction pattern that is substantially the same as Figure 1.

2. An isolated compound, which is topotecan monohydrochloride pentahydrate, said compound having an inverse second derivative FT-IR spectrum for the spectral region of 1800 cm^{-1}- 1500 cm^{-1} that is substantially the same as Figure 3.

3. An isolated compound, which is topotecan monohydrochloride pentahydrate, wherein said compound provides an x-ray diffraction pattern having peaks at 4.5 ± 0.1 (º 2θ), 6.4 ± 0.1 (º 2θ), 7.1 ± 0.1 (º 2θ), 9.0 ± 0.1 (º 2θ), 10.1 ± 0.1 (º 2θ), 11.5 ± 0.1 (º 2θ), 12.6 ± 0.1 (º 2θ), 13.1 ± 0.1 (º 2θ), 14.1 ± 0.1 (º 2θ), 15.5 ± 0.1 (º 2θ), 17.9 ± 0.1 (º 2θ), 18.7 ± 0.1 (º 2θ), 20.0 ± 0.1 (º 2θ), 20.3 ± 0.1 (º 2θ), 21.1 ± 0.1 (º 2θ), 21.8 ± 0.1 (º 2θ), 23.0 ± 0.1 (º 2θ), 24.8 ± 0.1 (º 2θ), 25.6 ± 0.1 (º 2θ), 26.6 ± 0.1 (º 2θ), 27.2 ± 0.1 (º 2θ), and 28.9 ± 0.1 (º 2θ).

4. An isolated compound, which is topotecan monohydrochloride pentahydrate, wherein said compound provides an FT-IR spectrum having peaks at 1754 ± 2 cm^{-1}, 1745 ± 2 cm^{-1}, 1740 ± 2 cm^{-1}, 1658 ± 2 cm^{-1}, 1649 ± 2 cm^{-1}, 1596 ± 2 cm^{-1}, 1584 ± 2 cm^{-1}, and 1507 ± 2 cm^{-1}.

5. The isolated compound according to any one of claims 1-4, wherein the topotecan monohydrochloride pentahydrate has a water content range between from about ≥ 10% w/w% to about ≤ 17 w/w%.

6. The isolated compound according to any one of claims 1-5, wherein the topotecan monohydrochloride pentahydrate has a water content in a range of about 10.5 wt% to about 16.5 wt%.

7. The isolated compound according to any one of claims 1-6, wherein the topotecan monohydrochloride pentahydrate has a crystalline lattice structure which incorporates three crystal lattice bound water molecules therein.

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8. The isolated compound according to any one of claims 1-7, wherein the topotecan monohydrochloride pentahydrate has a crystalline lattice structure which incorporates two coordinatively labile channel water molecules.

9. A pharmaceutical composition comprising the compound according to any one of claims 1-8 and a pharmaceutically acceptable carrier.

10. A pharmaceutical composition according to claim 9, wherein the pharmaceutical composition is a hard gelatin capsule and the pharmaceutically acceptable carrier comprises glyceryl monostearate and hydrogenated vegetable oil

11. A process for preparing the isolated compound according to any one of claims 1-8, wherein the process comprises steps of:

[a] forming an aqueous organic solvent mixture containing topotecan monohydrochloride;

[b] recrystallizing the topotecan monohydrochloride from and/or slurrying the topotecan monohydrochloride with the aqueous organic solvent mixture to precipitate and/or form the topotecan monohydrochloride pentahydrate product; and

[c] collecting, by filtration, said compound.

12. The process according to claim 11, wherein the aqueous organic solvent mixture comprises a mixture of acetone and a 0.05 N aqueous hydrochloric acid solution.

13. The process according to claim 12, wherein the ratio of the volume of acetone to aqueous hydrochloric acid is about 2:1.

14. The process according to claim 11, wherein the aqueous organic solvent mixture is heated to a temperature of about 58ºC.

15. The process according to claim 14, wherein the heated aqueous organic solvent mixture is cooled at a rate in the range of about 0.1ºC/min to about 1ºC/min.

16. The process according to claim 15, wherein the cooling rate is about 0.25°C/min.

17. The process according to claim 11, wherein the aqueous organic solvent mixture comprises an organic solvent and an aqueous solvent in a ratio of about 2:1.

18. A method of treating cancer which comprises administering to a subject in need thereof an effective amount of the compound according to any one of claims 1-8.

19. A method of treating cancer which comprises administering to a subject in need thereof an effective amount of the pharmaceutical composition according to claim 9.

20. The method according to claim 18 or claim 19, wherein said cancer is selected from the group of solid tumor types and non-solid tumor types.

21. The method according to claim 18 or claim 19, wherein said cancer is selected from the group of ovarian cancer, breast cancer, endometrial cancer, esophageal cancer, small and non-small cell lung cancer, cervical cancer, colorectal cancer, neuroblastomas and glioma.

22. The method according to claim 18 or claim 19, wherein said cancer is selected from the group of myelodysplastic syndrome, acute myelogenous leukemia and chronic myelomonocytic leukemia.

23. A method for ameliorating one or more of the symptoms associated with cancer, which comprises administering to a subject in need thereof an effective amount of the compound according to any one of claims 1-8.

24. A method for ameliorating one or more of the symptoms associated with cancer, which comprises administering to a subject in need thereof an effective amount of the pharmaceutical composition according to claim 9.

25. The method according to claim 23 or claim 24, wherein the one or more symptoms associated with cancer are selected from the group: pain, fatigue, insomnia, interference with daily activity, dyspnea, chest pain, hemoptysis and hoarseness.

26. Isolated topotecan monohydrochloride pentahydrate according to any one of claims 1-8 for use in therapy.

27. Use of the isolated topotecan monohydrochloride pentahydrate according to any one of claims 1-8 in the preparation of a medicament for the treatment of cancer.

28. Use of the isolated topotecan monohydrochloride pentahydrate according to any one of claims 1-8 in the preparation of a medicament for ameliorating one or more of the symptoms associated with cancer.